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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10 024,043	12 21 2001	Wilson Burgess	CI-0013	7597

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FLESHNER & KIM, LLP
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EXAMINER

AFREMOVA, VERA

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 01/30/2003

✓

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/024,043

Applicant(s)

Burgess et al.

Examiner

Vera Afremova

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 26, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-104 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-104 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-946) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) | 6) <input type="checkbox"/> Other |

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DETAILED ACTION

Claims 1-104 are pending and subject to restriction requirement.

Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1 and generic claims 6-18, 27, 28, 39-53, 81-88, drawn to a first method for sterilizing heart valves by irradiating, classified in class 435, subclass 1.1, for example.
- II. Claims 2, 3 and generic claims 5-53, 64-75, 79-88, 90, 91, 102, drawn to a second method for sterilizing heart valves by irradiating and one stabilizing protocol, classified in class 435, subclass 1.1, for example.
- III. Claim 4 and generic claims 5-53, 64-75, 90, 91, 98-102, drawn to a third method for sterilizing heart valves by irradiating and two stabilizing protocols, classified in class 435, subclass 1.1, for example.
- IV. Claim 54 and generic claim 63, 76 and 77, 104, drawn to a first composition with heart valves and a stabilizer, and generic claim 89, drawn to a sterile heart valve product which is sterilized by irradiation, classified in class 623, subclass 2.1, for example.
- V. Claim 55 and generic claims 56-63, 92, 93, 104, drawn to a second composition with heart valves and solvent, and generic claim 89, drawn to a sterile hear valve

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product which is sterilized by irradiation, classified in class 623, subclass 2.1, for example.

- VI. Claim 78, drawn to a method for prophylaxis and treatment of condition or disease in mammal with a sterilized heart valve product, classified in class 424, subclass 9.1, for example.
- VII. Claims 94-98, 103, 104, drawn to a third composition with heart valves, stabilizer and non-aqueous solvent, and generic claim 89, drawn to a sterile hear valve product which is sterilized by irradiation, classified in class 623, subclass 2.1, for example.

The inventions are distinct, each from the other because of the following reasons:

The instant application contain claims drawn to several inventions such as several methods of making products and several products. The claimed methods require different active steps and/or different protocols. For example: the Group II method (claims 2, 3) and the Group III method (claim 4) are different with regard to at least one distinct stabilizing protocol as claimed. But the stabilizing protocols are not required by the Group I method (claim 1) unlike the methods of Group II and III. Some claims are generic and they join the Group I, II or III to the extend of their applicability to the major active steps required by each method of making.

The claimed heart valve products are different and they require different components for stabilization of the final products as claimed. The heart valve product of Group IV (claim 54) require a stabilizer which is not required by the Group V heart valve product (claim 55) as

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claimed. The heart valve product of Group VII (claims 94 and 103) require both stabilizer and solvent as claimed. The product of claim 89 is generic and it joins any of the Group IV, V or VII product to the extent of a presence of the final components in the final product made by method.

Therefore, the inventions I-V and VII which are listed above are distinct because the products are made by materially different process as claimed. Moreover, various biological tissues and organs including heart valves, cartilage, ligaments and veins can be sterilized by irradiation. See US 5,534,026 (col. 1, lines 52-55). (MPEP § 806.05(f)).

The Group VI invention, drawn to a process of use of the product, is distinct for the inventions drawn to the products because the process for using the heart valve product for prophylaxis and treatment of condition or disease in mammal can be practiced with another materially different heart valve product which is sterilized with alcohol, for example: see US 6,383,732 (col. 5, line 14 and lines 40-45). (MPEP § 806.05(f)).

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches (as indicated by different classification). The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the Invention one group would not necessarily anticipate or make obvious any of the other groups. For these reasons restriction for examination purposes is proper.

Applicants are advised that the response to this requirement to be complete must include

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an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova

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January 28, 2003.

VERA AFREMOVA

PATENT EXAMINER

